K023132

DEC 17 2002

510 (K) Summary

Submitter:	Jostra AG Hechinger Straße 38 72145 Hirrlingen Germany
Contact Person:	Kathleen Johnson Phone: (302) 521-9469 Fax: (281) 292-7930
Date Prepared:	September 16, 2002
Device Trade Name:	Jostra Mecc System
Common/Usual Name:	Extracorporeal Circuit
Classification Names:	Cardiopulmonary bypass vascular catheter, cannula, or tubing Cardiopulmonary bypass adaptor, stopcock, manifold, or fitting Cardiopulmonary bypass blood reservoir Non-roller-type cardiopulmonary bypass blood pump Cardiopulmonary bypass pump speed control Cardiopulmonary bypass oxygenator Cardiopulmonary bypass arterial line blood filter
Predicate Device:	Bentley Duraflo Treated Extracorporeal Circuit

Device Description:

The Jostra Mecc System is a finished, sterile device for single use only and not to be resterilized by the user. The Jostra Mecc System is an extracorporeal circuit including circulatory and gas exchange support devices for use during extracorporeal circulation lasting 6 hours or less.

Indications for use:

The Jostra Mecc System is intended for use in surgical procedures requiring extracorporeal circulation and gas exchange support for 6 hours or less.

Statement of Technical Characteristics Comparison:

The Bentley Duraflo Extracorporeal circuit provides a user defined tubing circuit and may provide other user specified components such as pump, gas exchange device, reservoir and filter packaged together as a "custom tubing pack". The Jostra Mecc

System provides the same components assembled to the manufacturer's specifications.

All devices have previous 510(K) market clearance, have the same intended use, and have been validated for assembly into an extracorporeal circuit. The instructions for the Jostra Mecc System address safety issues regarding the use of a closed loop extracorporeal circuit.

Conclusion:

The Jostra Mecc System is substantially equivalent to the currently marketed predicate devices for the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 17 2002

Jostra AG
c/o Ms. Kathleen Johnson
Jostra-Bentley Corp.
2828 N. Crescent Ridge Drive
The Woodlands, TX 77381

Re: K023132
Jostra Mecc System
Regulation Number: 870.4360
Regulation Name: Non-roller type CPB pump
Regulatory Class: Class III (three)
Product Code: KFM
Dated: September 16, 2002
Received: September 20, 2002

Dear Ms. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number:

Device Name: JOSTRA MECC SYSTEM

Indications for Use
The Jostra Mecc System is indicated for use in surgical procedures requiring extracorporeal circulation and gas exchange support for 6 hours or less.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

X Prescription Use

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K023132